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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,084	12/05/2005	Christine Vauthier	BJS-1721-89	9469

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,084	VAUTHIER ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *7 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Apr. 28, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. Applicant's response to the Requirement for Restriction, filed on November 6 and 29, 2006 is acknowledged. The Examiner appreciates Mr. Sadoff's efforts to communicate with Applicant and clarify Applicant's elections.

Applicant has elected the invention of Group I, Claims 1-10, drawn to a compound comprising a hemoprotein associated with a sequenced block copolymer comprising a hydrophilic segment that is an oligosaccharide or a polysaccharide linked to at least one hydrophobic segment of Formula I and a method of using said compound as a human or animal blood substitute. Claims 11-13 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Within Group I, Applicant has elected the "X" moiety species to be CN, as recited in Claims 1 and 4. Claim 7 is pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Within Group I, Applicant has elected the "Y" moiety species to be of the formula "COOR-prime", as recited in Claim 1.

Within Group I, Applicant has elected the hemoprotein species "i", wherein the hemoprotein is a "normal hemoprotein" as recited in Claim 2.

Within Group I, Applicant has elected the hydrophilic segment species "ix", wherein the hydrophilic segment is heparin, as recited in Claim 6.

2. Election of Applicant's invention(s) was made with traverse.

Applicant argues that the Examiner did not properly support the restriction by providing a reference teaching the lack of a single general inventive concept under PCT Rule 13.1. Applicants' arguments have been fully considered but are not found persuasive. The Examiner reminds Applicant that the International Search Report found that the invention(s) claimed in the prior-filed application, PCT/FR03/01435, also claimed in the instant application, cannot be

considered novel or cannot be considered to involve an inventive step ("X" reference Bourdon et Debuire, 2002, * of record). Thus, the general inventive concept identified by Applicants does not define a special technical feature distinguishing the claimed invention over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Amendments

Applicants' amendments to the claims, filed December 5, 2005, is acknowledged.

3. Claims 7 and 11-13 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

4. Claims 1-6 and 8-10 are under consideration.

Priority

5. This application is a 371 of PCT/FR03/01435, filed June 10, 2003, which claims benefit of the foreign application FR 02/11518, filed September 17, 2002. Applicant's claim for the benefit of the prior-filed application, PCT/FR03/01435, under 35 U.S.C. 120 or 365(c) is acknowledged. A certified copy of the foreign patent application FR 02/11518 has been filed with the instant application; however, an English translation of said application has not been filed.

Accordingly, the effective priority date of the instant application is granted as June 10, 2003.

If Applicant believes the earlier applications provide support for this disclosure, Applicant should point out such support by page and line number in the reply to this Action.

Information Disclosure Statement

Applicant has filed an Information Disclosure Statement on April 28, 2005, which has been considered. The signed and initialed PTO Form 1449 is mailed with this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

6. **Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(a)** as being anticipated by Bourdon and Debuire (* of record in IDS).

Bourdon and Debuire teach the synthesis of nanoparticles for use as a blood substitute compatible with humans, the nanoparticles comprising polycyanoacrylate and the polysaccharide heparin, the nanoparticles further comprising hemoglobin.

Thus, Bourdon and Debuire anticipate Claims 1-6 and 8-10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

7. **Claims 1-6 and 8-10 are rejected under 35 U.S.C. 103(a)** as being obvious over Chauvierre et al, WO 02/39979 A1) and Desai et al (U. S. Patent No. 6,096,331).

Chauvierre et al teach the synthesis of nanoparticles of 1nm to 1mm (pg 7, line 30; pg 9, line 5) comprising a block copolymer comprising at least one segment having the formula as taught in Formula I (pg 3, lines 12-28), wherein "X" may be a "CN" moiety, wherein the hydrophobic segment may be a poly(alkylcyanoacrylate) (pg 8, line 29-pg 9, line 3) conjugated to a hydrophilic saccharide that may be heparin (pg 5, line 29; pg 9, line 1). Chauvierre et al teach that the inventive delivery system(s) may be used to administer a therapeutic agent to an animal or patient (pg 1, line 15; pg 9, lines 22-24).

Chauvierre et al do not teach the use of the heparin-coated poly(cyanoacrylate) nanoparticle for the delivery of hemoproteins such as hemoglobin. However, at the time of the invention, Desai et al taught the synthesis of nanoparticles comprising synthetic block copolymers (column 10, lines 3-22), attached to biocompatible materials, i.e. polysaccharides (column 9, lines 42-49). Desai et al do not explicitly disclose heparin as a contemplated polysaccharide; however, absent evidence to the contrary, the art recognizes that heparin is a polysaccharide. Desai et al also contemplate that hemoglobin would be present in the polymeric shell (column 9, line 54; column 11, line 63), thereby providing a blood substitute.

It would have been obvious to one of ordinary skill in the art to modify the nanoparticle of Chauvierre et al to include a hemoprotein such as hemoglobin as taught by Desai et al with a reasonable chance of success because Desai et al teach that the biocompatible agent, that is,

hemoglobin may be associated with the nanoparticle shell comprising a polysaccharide so as to be useful as a blood substitute.

An artisan would have been motivated to add hemoglobin to the nanoparticle of Chauvierre et al because the heparin moiety, well known in the art to act as an anti-coagulant as well as to inhibit complement activation, already tailors the nanoparticle for increased circulating half-life of the nanoparticle, and thus would provide an artisan with the desired delivery vehicle for a blood substitute.

Thus, Claims 1-6 and 8-10 are *prima facie* obvious.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Hill

Q. JANICE LI, M.D.
PRIMARY EXAMINER